DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2003

Mr. Al Flory
Vice President, Clinical
and Regulatory Affairs
St. Jude Medical
Cardiac Surgery Division
Anastomotic Technology Group
6500 Wedgwood Road
Maple Grove, Minnesota 55311

Re: K003446
Trade/Device Name: Symmetry Aortic Clip System
Regulation Number: 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NCA
Dated: February 16, 2001
Received: February 20, 2001

Dear Mr. Flory:

This letter corrects our substantially equivalent letter of May 21, 2001 regarding the Symmetry Aortic Clip System. We have corrected the product code from FZP to NCA.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003446S1

510(k) Number (if known): K003446

Device: Mechanical Anastomosis System

Indications for Use:

The Aortic Connector System is intended to create the aortic anastomosis of aortic autologous vein grafts.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003446

MAY 21 2001

K003446S1

510(k) Summary

Aortic Connector System

Common/Classification Name: Implantable Clip and delivery system as classified under 21 CFR 878.4300 and 4800

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Anastomotic Technology Group
6500 Wedgwood Rd.
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Contact: Milana Solganik, Director of Regulatory Affairs

Prepared: November 1, 2000

A. Legally Marketed Predicate Devices

The Aortic Connector System is substantially equivalent to the U.S. Surgical AutoSuture Vascular Anastomosis Clip Cartridge and Applier (K970793).

B. Device Description

The Aortic Connector System is a mechanical device used to facilitate an aortic vein graft anastomosis. The connector replaces sutures to create a secure, patent, and reproducible anastomosis. The Symmetry Aortic Connector System consists of a self expanding implantable connector and delivery system.

C. Indications for Use

The Aortic Connector System is intended to create the aortic anastomosis of aortic autologous vein grafts.

D. Substantial Equivalence Summary

Both devices are intended to be used in creating vascular anastomoses. The St. Jude Medical Anastomotic Technology Group Mechanical Anastomosis Connector is made of a Nickel Titanium alloy (Nitinol) in a "U" shape with rounded ends. The U.S. Surgical clip is made of Titanium in a "C" shape with blunted ends. The ends of both clips pinch the edges of the vessels together without penetrating the vessel wall.

The primary difference between the devices is the delivery method. The U.S. Surgical applier fires the clips one at a time, and the applier must be manually moved circumferentially around the anastomosis site. The St. Jude Medical Anastomotic

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Technology Group Mechanical Anastomosis Connector is a unitary device with all clipping elements being deployed simultaneously around the circumference.

E. Technological Characteristics

See **Device Description** above.

F. Testing

Mechanical, In Vitro, and animal, testing has been conducted which demonstrates that the performance of the Aortic Connector System is equivalent to standard suture anastomoses.

G. Conclusion

St. Jude Medical has demonstrated through its comparison of performance with standard suture anastomoses that the Aortic Connector System is equivalent to the predicate device.